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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,099	03/19/2004	Chunhui Xu	099/004P	7715

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EXAMINER	
NOBLE, MARCIA STEPHENS	
ART UNIT	**PAPER NUMBER**
1632	

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10/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/805,099	XU ET AL.	
	Examiner	Art Unit	
	Marcia S. Noble	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/11/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/11/2007 has been entered.

Status of Claims

2. Claims 1-10 are pending. Claims 1, 2, 8, and 10 are amended, by the amendment filed 7/11/2007. Claims 1-10 are under consideration.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 7/11/2007 was filed after the mailing date of the Office Action on 4/11/2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

4. Claim 1 is objected to for reciting in b) ""differentiate into areas". Cells do not differentiate into "areas". They differentiate into cell with a differentiated phenotype. In the instant case, the cells differentiated into cells that undergo spontaneous contraction.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

5. The rejection of claims 1-10, under 35 U.S.C. 112, first paragraph, as containing new matter in their recitations, "combining cell fractions" and "culturing the initiated cells so that they differentiate", is withdrawn.

Applicant amended the claims and claim no longer recite these recitations. Therefore, the rejection is withdrawn.

Scope of Enablement

6. Upon consideration of the amended claims, the scope of enablement rejection has been modified.

Claims 1-10 as amended, previously presented, and originally presented, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being

enabling for a method of generating cardiomyocytes and cardiomyocyte precursor cells from human embryonic stem (hES) cells obtained from a human blastocyst comprising initiating differentiation of the hES by forming embryoid bodies (EB) in suspension culture wherein some hES cells of the EB differentiate into cells that undergo spontaneous contraction, harvesting the differentiated cells that demonstrate spontaneous contraction, separating the harvested cells into factions by gradient density centrifugation, collecting the fractions with a density of between ~1.05 and ~1.075 g/mL, and isolating the cells from the collected fractions that express cardiac tronin I (cTnI), cardiac troponin T (cTnT), atrial natriuretic factor (ANF) or α-cardiac myosin heavy chain (MHC), thereby generating a cell composition comprising cardiomyocytes and cardiomyocyte precursor cells, and while being enabled for the above disclosed method wherein initiating differentiation occurs in a growth environment comprising serum, activin, insulin-like growth factor (IGF) and TGFβ , does not reasonably provide enablement for 1) a method of generating cardiomyocytes comprising collecting cells from any fraction of the gradient density centrifugation; 2) a method of generating cardiomyocytes comprising by differentiating hES cells in a growth environment comprising any morphogen and any growth factors and without serum; and 3) a method of generating a cell composition containing cardiomyocytes or cardiomyocytes precursor cells only.

While determining whether a specification is enabling, one considers whether the claimed invention provides sufficient guidance to make or use the claimed invention, if not, whether an artisan would require undue experimentation to make and use the

claimed invention and whether working examples have been provided. When determining whether a specification meets the enablement requirements, some of the factors that need to be analyzed are: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and whether the quantity of any necessary experimentation to make or use the invention based on the content of the disclosure is "undue".

Furthermore, USPTO does not have laboratory facilities to test if an invention will function as claimed when working examples are not disclosed in the specification, therefore, enablement issues are raised and discussed based on the state of knowledge pertinent to an art at the time of invention, therefore skepticism raised in the enablement rejections are those raised in the art by artisans of expertise.

1) The breadth of the claims encompass a method of generating cardiomyocytes comprising collecting cells from any fraction of the gradient density centrifugation.

The instant method combines a series of isolation and selection procedures to obtain an enriched population of cardiomyocytes and cardiomyocyte precursors that are delineated from hES cells, which is a method that is considered to be highly variable in the art (See page 199, col 1, lines 1-6; p. 205-207 of Pandur, Biol Cell 97:197-210, 2005). The methods disclosed in working examples of the specification teach that one characteristic of cardiomyocytes and cardiomyocyte precursor cells that can be used for further selection is cell density. The specification discloses that an enriched population of cardiomyocytes and cardiomyocyte precursor cells that have already been selected

for the phenotypic characteristic of spontaneous contraction ("beating") can be further enriched by collecting cells that are present in fractions I and II of a Percoll gradient with a density between ~1.05 g/mL and ~1.075 g/mL following gradient density centrifugation (p. 29 of the specification, lines 20-29). These finding are consistent with findings reported in the art for delineating mES cells into cardiomyocytes and cardiomyocyte precursor cells using density gradient centrifugation (Doevendans et al., J Mol Cell Cardiol 32:839-851, 2000, of record; see page 840). Therefore, the scientific logic, art, and specification would suggest that the densities corresponding to fraction I and II of a density gradient between ~1.05 g/mL and ~1.075 g/mL can serve as a type of selective marker for enriched populations of cardiomyocytes and cardiomyocytes precursors that have been previously demonstrated to undergo spontaneous contraction.

However, the breadth of the claims encompasses collecting cells from any fractions corresponding to any density, which would not be using the selective advantage provided by the density gradient centrifugation step disclosed in the specification and the art. The specification and the art do not disclose other densities that comprise cells expressing cardiac specific markers, such as cTnI, CTnT, and ANF as claimed, and that would provide an enriched population of cardiomyocytes and cardiomyocyte precursors. Therefore, an artisan would not know how to use any other fractions corresponding to any other densities to obtain such an enriched population of cardiomyocytes and cardiomyocyte precursor cells. Therefore, the specification does not provide guidance for the use of any other fractions corresponding to any other

densities than those of fractions I and II between ~1.05 g/mL and ~1.075 g/mL and therefore does not enable the use of any density as encompassed by the claims.

2) The breadth of the claims encompass a method of generating cardiomyocytes comprising by differentiating hES cells in a growth environment comprising any morphogen and any growth factors. The specification provides examples of the use of activin, IGF, and TGFβ in the EB cultures that resulted in enhanced proportions of beating cells bearing characteristic features of cardiomyocytes (p. 33, lines 1-30). These findings are consistent with findings in the art that suggest that treatment of human EB cells with activin and TGFβ direct differentiation along a mesodermal cell linage (Schuldiner et al PNAS 97(21):11307-11312, 2000).

However, the breadth of the claims encompass the use of any morphogen and any growth factors. However, the specification only teaches the subset of growth factors comprising activin, IGF, and TGFβ and the art at the time of filing and post-filing suggest that growth factor milieu necessary to delineate cardiomyocytes and cardiomyocyte precursor cells from human ES cells as not been well established and encompass many unknown contributory factors that lead to unpredictabilities.

Pandur discusses the many growth factors and combinations of growth factors that have been demonstrated to be involved in cardiomyocyte delineation of ES cells. Pandur also discusses many in vivo and ex vivo experiments used to try to elucidate which factors can be used to direct differentiation hES cells into cardiomyocytes and cardiomyocyte precursors (see pages 199-204). Pandur also specifically points to Schuldiner et al which cultures human EB cells with 8 different growth factors and

morphogens to determine how these factors will delineate the cells from the human EB and states, "As expected, none of these growth factors directed differentiation into a single, specific lineage." (see page 204, col 1, end of par 1). Pandur also concludes that the right mixture of growth factors necessary to induce cardiac differentiation of hES cells is obviously rather difficult and has not been established (p. 205, col 1) and states that this is in part due to the fact that the molecular mechanisms underlying the induction of cardiogenesis are nebulous (p. 199, col 1). Therefore, the post-filing art of Pandur demonstrates that at the time of filing the state of the art of which growth factors would result in differentiation of hES cells into cardiomyocytes and their precursors is rudimentary and that the morphogen and growth factor milleu necessary to direct differentiation of hES into cardiomyocytes is not well established and unpredictable.

Since the state of the art at the time of filing and post-filing suggests unpredictability, an artisan would look to the specification for specific guidance disclosing how to use the instant invention with any morphogen and any growth factors, as embraced by the claims, to overcome such unpredictabilities taught in the art. However, the instant specification fails to provide guidance correlating use of growth factors other than activin, IGF, and TGFβ to enhance the number of beating cells produced by the human EB. Therefore, the specification only enables the use of activin, IGF, and TGFβ to enhance the number of beating cells produced by the human EB.

Furthermore, the art of Schuldiner et al demonstrates that not all morphogens and growth factors will function to differentiate hES cells into cardiomyocytes and their precursors. Schider et al demonstrated that treatment of hES cells, pre-cultured in EB,

with the morphogen, BMP-4, directed the ES cells down an bone and ectodermal linage not a cardiac lineage (p. 11311, therefore demonstrating that not all morphogens and growth factors will differentiate stem cells along a cardiomyocyte linage as is encompassed by the claims. Again, an artisan would look to the specification for guidance on which morphogens and growth factors would differentiate ES cells along a cardiomyocyte lineage and the specification only teaches the subset of activin, IGF, and TGF. Therefore, the specification only enabled the use of activin, IGF, and TGFβ.

Given the lack of specific guidance provided by the specification as to specific growth factor that could be used other than activin, IGF, and TGFβ, it would have required undue experimentation for one of skill to use the methods as claimed with a reasonable expectation of success.

The claims also encompass a method of generating cardiomyocytes or cardiomyocyte precursors that does not include the use of serum in the culture of the hES cell. However, Pandur states, "The majority of experiments are currently being done using medium that is supplemented with fetal calf serum, which contains an undefined mixture of growth factors and other ingredients. Therefore, a cardiac-promoting or –inhibiting role of a molecule of interest has to be seen in the context of the culture conditions." (see page 205, col 2). Overall, Pandur and scientific logic suggests that it is unknown what types of contributions are being made by the factors present and influential in serum and their influence in the process of cardiac differentiation can not be overlooked and until the active components of serum are

elucidated serum as a whole must be considered an essential element for the differentiation of the hES cells into cardiomyocytes or their precursors.

Since the active factors of serum are not known in the art, an artisan would look to the specification for guidance as to the essential elements necessary from serum or means of serum-free culture to overcome the unknowns described in the art. However, the specification fails to provide guidance correlating to serum-free culture or the essential elements necessary from serum. It is unpredictable for the skilled artisan to use the instant method to generate a cardiomyocytes or their precursors without the use of serum as is encompassed by the claims. Therefore, the instantly claimed method is not enabled for a serum free culture for the differentiation of hES cells into cardiomyocytes or their precursors.

Given the lack of guidance provided by the specification as to use the instant method under serum-free conditions, it would have required undue experimentation for one of skill to use the methods as claimed with a reasonable expectation of success.

3) The instant claims encompass a method of generating a cell composition containing a relatively pure population of cardiomyocytes or a relatively pure population of cardiomyocytes precursor cells, as previously addressed in the Office Actions mailed 7/13/2006 and 4/11/2007. This is because the claims are stated in the alternative as a cell composition containing cardiomyocytes or cardiomyocyte precursors.

As previously stated in the Office Action, mailed 7/13/2007 (pages 6-7), "The instant invention claims a method comprising generating a cell composition containing cardiomyocytes or cardiomyocytes precursor cells only. However the art suggest that

obtaining a homogenous cell population following the differentiation of stem cells in not possible and would be highly unpredicatable.

Verfaillie *et al.* [**Hematology** (Am Soc Hematol Educ Program). 2002;:369-91] who review the state of the art of stem cells at the time of filing, teach, that, with regard to the directed differentiation of ES cells, "Many proposed applications of human ES cells are predicated on the assumption that it will be possible to obtain pure populations of differentiated cells from the ES cultures. It might be envisioned that in order to achieve this one would treat ES cells with inducing agents that would convert them with high efficiency to a cell type of interest. In practice, that has not proven possible with the mouse system." See p. 278, 2nd column, Differentiation in vitro. They further teach that a range of approaches have been attempted to produce a highly homogenous population of differentiated cells from ES cells, for example, relying upon the spontaneous differentiation of the ES cells to embryoid bodies. However, embryoid bodies contain a range of differentiated cells, which is a recognized limitation of directed differentiation of ES cells. Verfaillie teach that the ES cells can be treated with particular agents/factors that can drive differentiation along a specific lineage (see p. 379, 1st column, 1st full ¶. However, it is clear that directed differentiation of ES cells to generate a particular cell type of interest is unpredictable. Thus, specific guidance must be provided to enable the claimed invention. Therefore, any cell composition produced by driven differentiate as claimed will also comprise a percentage of other cells types. Since the art suggest that a homogenous cell composition is not possible and the art does not provide guidance to overcome these obstacles presented in the art, the instant

specification does not enable a method of generating a cell composition containing cardiomyocytes or cardiomyocytes precursor cells only."

These reasoning and statements by Veraillie are further supported by Pandur. Pandur states that cardiomyocyte differentiation is highly variable and the small clusters of cardiomyocytes produced from EB formation and growth factor treatment are part of a very heterogeneous population of cells (p. 199, col 1). Pandur in conclusion teaches that presently too many unknown factors impede our ability to control differentiation of hES cell into a homogenous cardiomyocyte precursor or fully differentiated cardiomyocyte population and at present production of heterogeneous populations of cells that have an increased number of cells that are along a cardiomyocyte lineage pathway is all that we can accomplish (p. 205-206).

As previously discussed the claims encompass generating a relatively pure population of cardiomyocytes that does not necessarily comprise cardiomyocyte precursor cells, a relatively pure population cardiomyocyte precursor cells that does not necessarily comprise cardiomyocytes, or even a combination population of cell of cardiomyocyte lineage at the exclusion of cell of non-cardiomyocyte lineage. However, the state of the art suggests that at this time such homogenous populations of cells are not possible because the art does not provide a means of controlling differentiation to the specific outcome of a cardiomyocyte or a cardiomyocyte precursor exclusively but only to a cardiomyocyte linage that would comprise a mixture of cells comprising cardiomyocytes and cardiomyocyte precursors. Furthermore, the specification does not provide any means of overcoming the obstacles taught in the art. Therefore, an artisan

would not know how to use the instant method to produce a homogenous population cardiomyocytes, a homogenous population of cardiomyocyte precursor cells, or even a population of cells that exclude non-cardiomyocyte cells as is embraced by the claims.

Again as discussed above, the claims read on relatively homogenous populations of cells because the claims are written in the alternative, "generating a cell composition comprising cardiomyocytes or cardiomyocyte precursor cells". If these claims were modified to represent a more mixed populations of cardiomyocytes and cardiomyocyte precursors, this would aid in some of the enablement issues discuss above and previous.

Applicant is not respond in their remarks filed 7/11/2007 to the enablement rejection of record. Therefore, for the reasons discussed above and previously made of record, the claims are not enabled for their full breadth.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. The rejection of claim 2 for its recitation of the trademark Matrigel™ is withdrawn. Applicant amended the claims to remove this recitation; therefore, the rejection is withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1, 2, 4, 7, 8 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 8-12 of copending Application No. 11/086,709. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed inventions have overlapping scope.

Applicant states that the instant rejection is provisional and if copending application becomes allowable prior to allowance of the current claims, Applicant will address the rejection on their merits or will file a terminal disclaimer. Applicant's statement is acknowledged and the rejection is maintained.

9. Claims 1-5, 7, 8, 10 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10, 12-18, and 20 of copending Application No. 11/040691

Applicant states that the instant rejection is provisional and if copending application becomes allowable prior to allowance of the current claims, Applicant will address the rejection on their merits or will file a terminal disclaimer. Applicant's statement is acknowledged and the rejection is maintained.pping scope.

10. Claims 1, 2, 6-8 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 and 16 of copending Application No. 11/085,899. Although the conflicting claims are not identical, they are not patentably distinct from each other because they have overlapping scope.

Applicant states that the instant rejection is provisional and if copending application becomes allowable prior to allowance of the current claims, Applicant will address the rejection on their merits or will file a terminal disclaimer. Applicant's statement is acknowledged and the rejection is maintained.

Conclusions

11. The instant claims appear to be free of the art. A review of the are also suggest that the instant inventors are one of the first, if not the first, to demonstrate spontaneous contractions of human EB cell outgrowths. Although the instant methods have been established in mouse ES cells this provides motivation but not a reasonable expectation

of success that the mouse methods can sucessfully be applied to hES. In fact, the unpredictabilities caused by differences in mouse ES cells and hES cell taught by the art of Pandur suggests that the methods and finding in mES cell differentiation into cardiomyocytes are not necessarily directly translatable to hES cells and their differentiation into cardiomyocytes (p. 25, col 2). Therefore, the art teaches away from a reasonable expectation of success or at least sheds doubt on a reasonable expectation of success for applying the mouse methods sucessfully to hES cells.

However, the unpredictabilities and rudimentary nature of art at the time of filing and post-filing also demonstrate that the instant claims are not enabled for their full breadth, and therefore, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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